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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/756,717

01/13/2004

Edward L. Sinofsky

CFI-5755CONT

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08/04/2008

EDWARDS LIFESCIENCES CORPORATION

LEGAL DEPARTMENT

ONE EDWARDS WAY

IRVINE, CA 92614

EXAMINER

JOHNSON III, HENRY M

ART UNIT

PAPER NUMBER

3730

MAIL DATE

DELIVERY MODE

08/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/756,717

Applicant(s)

SINOFSKY, EDWARD L.

Examiner

Henry M. Johnson, III

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I, claims 1-16 in the reply filed on February 12, 2008 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term housing or lumen impermeable to fluid is new matter. The term impermeable is not disclosed in the original disclosure rendering the term new matter. While it may appear to be obvious that the lumen is impermeable to fluid, use of such feature as a primary patentability factor requires a positive disclosure of the feature.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,910,129 to Koblish et al. in view of U.S. Patent 5,680,860. Koblish et al. disclose a device for cardiac ablation with multiple electrode structures comprising a housing with handle (Fig. 1, #

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18) and electrodes movable with a lumen that may form a loop (Figs. 36-40). A saline liquid is disclosed as being provided via the lumen for delivery to the treatment site via porous elements of the electrode assembly (Fig. 37). The electrode (Fig. 36, # 362) is movable within the lumen (Fig. 36, # 36) and when in position for ablation would be adjacent to the housing, the lumen inherently being impermeable to the fluid or it would be dispersed along the body housing.

Koblish et al. do not disclose laser as the ablation source. Edwards teaches that alternative suitable energy delivery devices include: (i) a radio-frequency (RF) source coupled to an RF electrode, (ii) **a coherent source of light coupled to an optical fiber**, (iii) an incoherent light source coupled to an optical fiber, (iv) a heated fluid coupled to a catheter with a closed channel configured to receive the heated fluid, (v) a heated fluid coupled to a catheter with an open channel configured to receive the heated fluid, (vi) a cooled fluid coupled to a catheter with a closed channel configured to receive the cooled fluid, (vii) a cooled fluid coupled to a catheter with an open channel configured to receive the cooled fluid, (viii) a cryogenic fluid, (ix) a resistive heating source, (x) a microwave source providing energy from 915 MHz to 2.45 GHz and coupled to a microwave antenna, (xi) an ultrasound power source coupled to an ultrasound emitter, wherein the ultrasound power source produces energy in the range of 300 KHZ to 3 GHz, or (xii) a microwave source (Col. 8, lines 33-51). It would have been obvious to one skilled in the art to use a laser as taught by Edwards in the invention of Koblish et al. as an alternative ablation energy source. The use of lasers as an ablation source is pervasive in the arts and a skilled artisan would provide the required reflectors, transmissive regions, etc. to insure the laser was delivered to the target area.

Regarding claims 6-9, the properties of the fluid are related to intended use and have no impact on the device structure.

Regarding claims 12 and 13, any fluid is capable of cooling and lubricating.

Regarding claims 10-16, the method of use is inherent in the combined invention of Koblisch et al. in view of Edwards.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,241,754 teaches laser as an alternative ablation energy source. U.S. Patent 5,680,860 teaches delivery ports at a distal end of a catheter for fluid delivery.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 5:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Henry M. Johnson, III/
Primary Examiner, Art Unit 3739

/HMJ/
8/2/2008